

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 39-86 are pending in the application, with claims 39 and 71 being the independent claims. The above-amendments are not believed to introduce new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Objections to the Drawings***

The Examiner objected to the drawings as not showing every feature of the claims. In particular, the Examiner objected to the drawings as not showing a dispensing device, a plug connection, a screw connection, a bayonet connection, a snap action connection, a welded thermoplastic material connection, snap hooks, an axis, the stiff outer casing being a unitary piece, and an atomizer.

The drawings show a dispensing device in Figures 1 and 2, and in particular, the upper portion 2 and the lower portion 3 of the dispensing device.

The drawings also show a plug connection. As explained at page 5, lines 19-23, "[t]he releasable connection between the cartridge and the connection portion of the dispensing device can be a plug-type connection in which the connection portion is provided with a plurality of snap hooks which engage into the peripherally extending groove in the upper part of the stiff casing after the cartridge has been inserted into the

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device." At least FIGs. 1 and 2 show the snap hooks 19 of the connection portion and the peripherally extending groove 11 of the stiff casing, thereby showing the plug connection recited in the claims. As noted, these drawings therefore also show the snap hooks. Although the drawings do not specifically show a bayonet connection or a screw connection, Applicants assert that these embodiments are sufficiently described in the specification such that drawings are not necessary. According to 37 C.F.R. § 1.81(a) drawings are only required "where necessary for the understanding of the subject matter to be patented... ."

The drawings also show the axis of the withdrawal connection portion 15. The axis is clearly depicted in at least FIGs. 1 and 2 by the dash-dot line running vertically through the center of the device.

Further, the stiff outer casing being a unitary piece is also shown. As noted above, drawings are not required for an understanding of constructing the stiff outer casing as a unitary piece or as two pieces connected together. The description at page 4, lines 2-7 is sufficient for a clear understanding of the invention.

Atomizers are well known in the industry. Drawings are only required if the invention cannot be understood without them. 37 C.F.R. § 1.81(a). Depicting a generic atomizer is unnecessary for the understanding of the described and claimed invention.

Accordingly, Applicants respectfully request that the objections be withdrawn.

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***Objections to the Specification***

The Examiner objected to the specification as not complying with the arrangement requirements and as lacking headings. The enclosed Substitute Specification corrects these informalities. No new matter has been added. Applicants therefore respectfully request entry of the Substitute Specification and withdrawal of the objection.

***Rejections under 35 U.S.C. § 112***

The Examiner made several rejections under 35 U.S.C. § 112, second paragraph, purporting that the claims were indefinite for not particularly pointing out and distinctly claiming the subject matter of the invention. Many of the rejections were based on antecedent basis. Although Applicants assert that the claims rejected clearly pointed out the subject matter being claimed, such as "the inside" of a container, Applicants have amended the claims above, thereby overcoming the rejections. Particular rejections are addressed in more detail below.

Claims 39 and 71 were rejected for the term "stable in respect of shape". The language has been amended to clarify that the container is "stable with respect to shape." This language more clearly provides that the container, regardless of its shape, is stable with respect to its shape, as opposed to a collapsible bag, for example, which changes shape depending on the amount of a substance contained therein.

Claim 53 was rejected due to the term "deep-drawn metal". Applicants assert that this term is well-known in the art. A search of the web for "deep-drawn metal" reveals several companies which make deep-drawn metal products, such as casings,

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shell, etc., for example <http://erniej.tripod.com/shells.htm>. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claims 70, 71, 73 and 74 were rejected due to the language "peripherally extending groove". Applicants assert that this language is clear, especially when read in light of the specification and drawings. It clearly means a groove extending around the periphery of the object, in this particular case, the stiff outer casing. Item 11 in the figures shows this peripherally extending groove.

Claims 59 and 60 were rejected because the Examiner asserted that the term "the recess" lacked antecedent basis. The term "recess" was recited in claim 58, from which claims 59 and 60 depend. Accordingly, there is sufficient antecedent basis for the term in these claims.

For the above-stated reasons, Applicants respectfully request that the rejections be withdrawn.

***Rejections under 35 U.S.C. § 103***

Claim 39-42, 45, 53-56, 71, and 75-80 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,255,972 to Hultgren ("the Hultgren '972 patent"). Applicants respectfully traverse the rejection.

The Examiner has made a strained reading of the Hultgren '972 patent, labeling items such at the top of cup-like casing 33 as the bottom and asserting that the extension 38 (which Applicants assume the Examiner considers the stopper) is releasably connected by the casing 33 to the container 34. The casing 33 of the Hultgren '972 patent in no way connects the extension 38 to the container 34, as recited in claim 39.

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Further, as properly interpreted and clarified in the amendment to claim 39 above, the casing 34 of the Hultgren '972 patent does not include an opening in its bottom. For at least these reasons, independent claim 39 of the present application is allowable over the Hultgren '972 patent. Claims 40-70 and 72-86 depend from and add features to independent claim 39, and are allowable for at least the same reasons thereof.

The Examiner asserts that claim 71 is equivalent to claim 40 and therefore does not address the rejection directly. However, claim 71 recites that the stiff outer casing includes a peripherally extending groove and the connection portion of the dispensing device includes snap hooks which engage the peripherally extending groove. The Hultgren '972 patent does not disclose such an arrangement. The head assembly 10 and the casing 33 are threadably engaged. See col. 2, lines 50-54. Accordingly, Applicants respectfully request that the rejection be withdrawn.

***Information Disclosure Statement***

The Examiner did not initial document nos. AL1 and AN1 submitted with Applicants Information Disclosure Statement. The Examiner does not provide a reason for not considering these documents. If the Examiner did not consider these documents because they were in a foreign language, the Information Disclosure Statement noted that a brief explanation of the documents is provided in the specification as filed. Applicants are submitting a Supplemental Information Disclosure Statement accompanying this Amendment. Applicants have re-listed document AL1 and AN1 and provided a brief explanation of their relevance in the body of the IDS, rather than referring to the

specification. Accordingly, Applicants respectfully request that the Examiner initial Form PTO-1449 to indicate consideration of these documents.

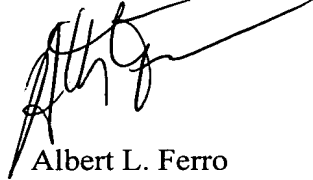
### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully  
requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'A. Ferro', is written over the printed name of the attorney.

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**Version with markings to show changes made**

Marked-up version of claim 39:

| ~~39~~. (Amended) A cartridge for a liquid, which can be connected to a dispensing device, the dispensing device including an upper portion for receiving the cartridge and a lower portion which can be pushed over the [connected] cartridge when connected to the dispensing device, the upper portion of the dispensing device being provided with a connection portion for the cartridge and with a dispensing connection portion for drawing off the liquid, the cartridge comprising:

a stiff outer casing including a top portion and a bottom portion, the top portion of the outer casing being coupled to the upper portion of the dispensing device;

a container which is stable [in] with respect [of] to shape and which is disposed in the outer casing; and

a collapsible bag disposed in the container and containing the liquid, wherein the bottom portion of the stiff outer casing [includes a bottom] is provided with an opening, and

wherein the container includes an opening and a stopper, the stopper including an insertion connection portion which forms a sealingly closing, centered guide means for the dispensing connection portion, and

wherein the stopper is non-releasably connected by the outer casing to the container, and

wherein the cartridge is releasably connected to the connection portion on the upper portion of the dispensing device.

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Marked-up version of claim 42:

4 ~~42~~. (Amended) A cartridge according to claim 39, wherein the stopper is connected to the container [in-force-locking and positively locking relationship by means of a snap connection.

Marked-up version of claim 46:

4 ~~46~~. (Amended) A cartridge according to claim 39, wherein the stopper is provided at an [the] end of the insertion connection portion with a diaphragm disposed inclinedly with respect to [the] an axis of the insertion connection portion.

Marked-up version of claim 47:

9 ~~47~~. (Amended) A cartridge according to claim 39, wherein a sealing disc provided with sealing beads is disposed between [the] an upper edge of the container and [the] an inside of the stopper.

Marked-up version of claim 48:

10 ~~48~~. (Amended) A cartridge according to claim 39, wherein [the] an inside of the stopper is provided with a sealing lip.

Marked-up version of claim 57:

11 ~~57~~. (Amended) A cartridge according to claim 39, wherein a projecting bead is provided at the bottom of the stiff outer casing [is provided at its bottom with a projecting bead].

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Marked-up version of claim 58:

58. (Amended) A cartridge according to claim 39, wherein the bottom of the stiff outer casing includes a recess [in its bottom].

Marked-up version of claim 59:

59. (Amended) A cartridge according to claim 58, wherein the stiff outer casing is provided within the recess with an opening with a [whose] diameter [in the case of a circular cross-section is] of between 0.1 millimeter and 5 millimeters.

Marked-up version of claim 60:

60. (Amended) A cartridge according to claim 58, wherein the stiff outer casing is provided within the recess with an insert including a micro-opening which communicates with the opening in the bottom of the stiff outer casing, and wherein if the mirco-opening is [which in the case of a] circular in cross-section, [is of] a diameter of the circular cross-section is between 10  $\mu\text{m}$  and 500  $\mu\text{m}$  and is of a length of between 100  $\mu\text{m}$  and 5000  $\mu\text{m}$ .

Marked-up version of claim 61:

61. (Amended) A cartridge according to claim 60, wherein the insert is provided with a filter [in front of] adjacent the micro-opening.

Marked-up version of claim 62:

62. (Amended) A cartridge according to claim 53, wherein the stiff outer casing is provided with at least one peripherally extending crease which embraces the stopper [in-force-locking and positively locking relationship].

Marked-up version of claim 64:

64. A cartridge according to claim 39 wherein an upper part of the stiff outer casing is provided [in its upper part] with a peripherally extending groove which embraces the lower edge of the stopper.

Marked-up version of claim 65:

65. (Amended) A cartridge according to claim 39 wherein an upper part of the stiff outer casing is provided [in its upper part] with a flanged-over portion which embraces the upper edge of the stopper.

Marked-up version of claim 66:

66. (Amended) A cartridge according to claim 39, wherein the cartridge is sealed adjacent [in the region of] the stopper by a diffusion-tight sealing foil.

Marked-up version of claim 67:

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67. (Amended) A cartridge according to claim 39, wherein an outside of the bottom of the stiff outer casing is sealed [on the outside of its bottom] by a diffusion-tight sealing foil.

Marked-up version of claim 68:

68. (Amended) A cartridge according to claim [39] 67, wherein provided in [the] a central region of the sealing foil on the outside of the bottom of the stiff casing is a free space which is covered by the sealing foil.

Marked-up version of claim 71:

71. (Amended) A releasable connection between a cartridge and [a connection portion of] a dispensing device, comprising:

a connection portion disposed on an upper portion of the dispensing device;

snap hooks provided on the connection portion which engage into a peripherally extending groove in a stiff outer casing [container which is stable in respect of shape], after the casing [container] has been pushed into the dispensing device.

Marked-up version of claim 72:

72. (Amended) A cartridge according to claim 67, wherein [the] an inside of the bottom of the lower portion of the dispensing device is provided with a piercing device for the sealing foil which is disposed on the [underside] outside of the bottom of the stiff outer casing.

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Marked-up version of claim 73:

73. (Amended) A cartridge according to claim 39 for an aqueous liquid, wherein the container and the stopper comprise polypropylene, further comprising a collapsible bag of polyethylene disposed in the container, wherein:

the stiff outer casing comprises a plastic material, preferably polypropylene;

the opening in the bottom of the stiff outer casing is a bore;

an end of the insertion connection portion is closed [at its end] by a diaphragm inclined with respect to [the] an axis of the insertion connection portion and the sealingly closing, centered guide means is a press fit and is connected by a snap connection to the container;

the cartridge is releasably connected to the connection portion by means of a releasable plug connection, the releasable plug connection being a snap connection in which there are provided in the connection portion of the upper portion of the dispensing device snap hooks which engage into a peripherally extending groove in [the] an upper region of the cartridge;

the bottom of the outer casing includes an inset with a micro-opening which communicates with [a] the bore in the outer casing; and

[the] an inside of the bottom of the [push-on] lower portion of the dispensing device is provided with a resilient piercing device for a sealing foil on [the] an underside of the bottom of the casing.

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Marked-up version of claim 74:

74. (Amended) A cartridge according to claim 39 for an alcoholic liquid, wherein the container and the stopper comprise polypropylene, further comprising a collapsible bag of polyethylene disposed in the container, wherein:

the stiff outer casing comprises a metal, preferably aluminum;

an end of the stopper is closed [at its end] by a diaphragm which is inclined to [the] an axis of the insertion connection portion;

the sealingly, closing guide means is in the form of a press fit;

the stopper is non-releasably connected by the outer casing to the container;

[the insertion connection portion is closed at its end by a diaphragm inclined with respect to the axis of the insertion connection portion and the sealingly closing, centered guide means is a press fit and is connected by a snap connection to the container, and]

the releasable [plug] connection between the cartridge and the connection portion of the dispensing device is in the form of a snap connection in which there are provided in the connection portion of the upper portion of the dispensing device snap hooks which engage into a peripherally extending groove in [the] an upper region of the cartridge[.];

[the] an inside of the bottom of the [push-on] lower portion of the dispensing device is provided with a resilient piercing device for a sealing foil on [the] an underside of the bottom of the casing.

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Marked-up version of claim 84:

84. (Amended) Use of the cartridge according to claim 74 containing a medical liquid for producing an inhalable aerosol for [the] treatment of illnesses.

Marked-up version of claim 85:

85. (Amended) Use of the cartridge according to claim 73 containing a medical liquid for producing an inhalable aerosol for [the] treatment of illnesses.

Marked-up version of claim 86:

86. (Amended) Use of the cartridge according to claim 39 containing a medical liquid for producing an inhalable aerosol for [the] treatment of illnesses.



Boehringer Ingelheim CARTRIDGE FOR A LIQUID

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International GmbH CROSS-REFERENCE TO RELATED APPLICATIONS

~~Cartridge for a liquid~~ This application claims the benefit under 35 U.S.C. § 119(e) to provisional application no. 60/165,915, filed November 17, 1999.

STATEMENT REGARDING FEDERALLY-SPONSORED  
RESEARCH AND DEVELOPMENT

Not applicable.

BACKGROUND OF THE INVENTION

Field of the Invention

The invention concerns a cartridge for a liquid, which can be connected to a draw-off or dispensing device. The dispensing device includes an upper portion which accommodates the cartridge and a lower portion which can be pushed on over the connected cartridge. The upper portion of the device is provided with a connecting portion for the cartridge and with a dispensing connection portion for drawing off and dispensing the liquid.

Liquids in accordance with the present invention can be solutions, suspensions or emulsions, Preferred liquids are those which contain an active substance. Active substances can be pharmacologically active substances for treatment of the human or animal body or active substances for diagnostic purposes or for a cosmetic use.

The invention aims to adapt an economically manufacturable cartridge of that kind to specific demands.

Background Art

Different thin-wall containers of the general kind set forth, for a liquid, are known, which are not diffusion-tight in relation to volatile constituents of the liquid. In that case a part of the



liquid is lost by diffusion and the level of concentration of constituents of the liquid changes in a manner which is possibly unacceptable. Containers of that kind are suitable for a relatively short storage time. In the case of other containers of the general kind set forth, unacceptable changes in the liquid occur due to diffusion or due to the action of air, prior to or during the period of use. Particularly in the case of containers for a liquid which contains medical active substances, there is a need to satisfy intensified demands in order to avoid unacceptable adverse effects on the quality of the medicament.

Accordingly the object of the invention is to develop a cartridge for a liquid, which can be economically produced even in large numbers and which in the filled condition can be stored over a long period of time even under difficult conditions. The invention seeks to provide that the liquid can be easily drawn off and not involve contact with the environment. The invention further seeks to provide that the cartridge can be connected to a draw-off or dispensing device as easily as possible and interchangeably and that the cartridge can be reliably handled even by unskilled persons. The invention further seeks to provide that the cartridge is also suitable for a liquid which contains medical active substances and satisfies the intensified conditions which occur in that situation.

### SUMMARY OF THE INVENTION

In accordance with the invention that object is attained by a cartridge which can be connected to a draw-off or dispensing device. The dispensing device includes an upper portion which accommodates the cartridge and a lower portion which can be pushed on over the connected cartridge. The upper portion of the device is provided with a connection portion for the cartridge and with a draw-off or dispensing connection portion for drawing off the liquid. The cartridge can be in the form of a triple-shell container comprising an outer stiff casing, a container which is stable ~~in~~ with respect ~~of~~ to shape and which is disposed in the casing, and a collapsible bag which is arranged in the container that is stable ~~in~~ with respect ~~of~~ to shape and which contains the liquid. The stiff casing can have a bottom which can be provided with an opening. The container which is stable ~~in~~ with respect ~~of~~ to shape can also have an opening and can be closed with a stopper provided with an insertion connection portion. The stopper can form a sealingly closing, ~~centred~~ centered guide means for the draw-off connection portion. The stopper can be non-releasably connected by the stiff casing to the container which is stable ~~in~~

[with] respect of [to] shape. The cartridge can be releasably connected to the connection portion at the upper portion of the dispensing device.

The connection between the cartridge and the connection portion of the device can be in the form of a plug-in connection, a screw connection or a bayonet connection. This connection can preferably be a releasable connection. Optionally, it can be in the form of a non-releasable connection or a connection which is difficult to release.

The stopper can preferably comprise a thermoplastic material and can be connected to the container that is stable in respect of shape, in force-locking and positively locking relationship, by means of a snap-action connection. The stopper can also be non-releasably welded to the container that is stable ~~in~~ with respect of to shape and that comprises thermoplastic material, by the materials merging together. The stopper can be provided in the insertion connection portion with a funnel-shaped centred guide means for the dispensing or draw-off connection portion. The guide means can be provided with guide ribs. The stopper can sealingly embrace the draw-off connection portion and can be in the form of a press fit for the latter. It may be desirable for the end of the insertion connection portion, that is towards the internal space of the collapsible bag, to be closed by a diaphragm which can be arranged inclinedly relative to the axis of the insertion connection portion and which can be pierced when the draw-off connection portion is introduced into the cartridge. That diaphragm prevents the liquid from escaping into the insertion connection portion during storage of the cartridge.

A sealing disc which can be provided with sealing beads or ridges can be provided between the upper edge of the container which is stable ~~in~~ with respect of to shape, and the inside of the stopper. The inside of the stopper can be provided with a sealing lip or a plurality of sealing lips which are pressed into the sealing disc on the upper edge of the container which is stable ~~in~~ with respect of to shape.

Apart from its opening, the stiff casing is diffusion-tight in relation to gases and liquids. This casing can be a one-piece deep-drawn metal casing, preferably of ~~aluminium~~ aluminum.

The stiff casing can also be of a two-piece construction; then, the two parts of the casing are joined together and sealed off relative to each other by way of sealing elements by welding or by adhesive. The stiff casing can also comprise a plastic material, preferably a thermoplastic material.

The stiff casing can have a projecting bead or ridge at the edge of its bottom. The bottom can be provided with a recess which is arranged centrally as an inwardly turned region of the bottom.

The stiff casing preferably has at the ~~centre~~ center point of the bottom an opening which can be in the form of a bore. It is additionally possible to provide in the recess in the bottom of the casing an insert which preferably comprises plastic material and which includes an opening in the form of a micro-opening which communicates with the opening in the bottom of the stiff casing. A filter can be disposed in front of the micro-opening within the insert.

The opening in the bottom of the stiff casing can be of a diameter of between 0.1 mm and 5 mm when the cross-section involved is circular. The micro-opening in the insert, when a circular cross-section is involved, is between 10 µm and 500 µm in diameter and between 100 µm and 5000 µm in length. The micro-opening makes it possible to adjust to a desired value the time for pressure ~~equalisation~~ equalization between the internal space in the cartridge and its environment.

The stiff casing of metal can be provided in the proximity of its open end with a peripherally extending crease which embraces the stopper in force-locking and positively locking relationship. The stiff casing of thermoplastic material can be welded to the stopper, with merging of the materials thereof. In addition in its upper part the stiff casing can be provided with a peripherally extending, outwardly open groove which extends around the lower edge of the stopper. At its open end the stiff casing may have a flanged-over portion which embraces the upper edge of the stopper.

The stiff casing can be provided with a plurality of projections which protrude into the interior of the casing and which support the container which is stable in respect of shape within the stiff casing. Preferably three projections are disposed in the middle to the lower region of the stiff casing, which are disposed in a plane which is perpendicular to the axis of the casing. In the case of a stiff casing of metal, those projections can be produced when flanging the open end of the stiff casing.

The cartridge can be sealed in the region of the stopper with a a-possibly diffusion-tight-sealing foil which closes the open end of the insertion connection portion. The outside of the casing bottom can also be provided with a a-possibly diffusion-tight-sealing foil which covers over the opening in the bottom or the insert in the bottom of the casing. Both sealing foils prevent the penetration of dirt into the openings beneath the foils and prevent the

diffusion of constituents of the liquid during the time for which the cartridge is stored. Both sealing foils are detached or pierced only immediately prior to first regular use of the cartridge.

The releasable connection between the cartridge and the connection portion of the dispensing device can be a plug-type connection in which the connection portion is provided with a plurality of snap hooks which engage into the peripherally extending groove in the upper part of the stiff casing after the cartridge has been inserted into the device. The plug connection can advantageously also be used for other containers of the general kind set forth, in which case the container which is stable in respect of shape or the stopper includes a groove into which the snap hooks engage.

Snap hooks of plastic material can be provided with a metal spring element which maintains the spring property of the snap hooks over a long period of time and at elevated temperature.

A free space which is covered by the sealing foil can be provided in the central region of the sealing foil on the outside of the bottom of the casing. A rigid or resilient piercing device can be disposed on the inside of the bottom of the lower portion of the device, the piercing device piercing the sealing foil disposed on the underside of the bottom of the casing, prior to the first withdrawal of a part of the liquid from the cartridge. That opens the opening in the bottom of the casing or the micro-opening in the insert and permits air to pass into the space inside the cartridge.

To remove a used cartridge from the dispensing device, it is possible to use a withdrawal aid which is pushed under the bead or ridge at the bottom of the stiff casing, thereby to make it easier to pull the cartridge out.

Before the cartridge is connected to the dispensing device, the sealing foils on the stopper and on the bottom of the cartridge are detached or those sealing foils are pierced when the cartridge is connected to the dispensing device. A difference in pressure which possibly prevails between the interior of the cartridge and the environment around the cartridge is ~~equalised~~ equalized through the opening in the bottom of the stiff casing.

When a quantity of liquid is drawn out of the cartridge connected to the dispensing device, the collapsible bag collapses and its volume is reduced by the volume of the quantity of liquid which is drawn off. As a result there is a reduced pressure in the gas space of the cartridge (this is the free space between the outside of the collapsible bag and the inside of the stiff casing) in comparison with the pressure in the ambient atmosphere around the cartridge. That pressure

difference is ~~equalised~~ equalized in a relatively short period of time if the stiff casing is thin-walled and is provided with a bore in the region of between 0.1 mm and 5 mm.

If the cartridge is provided in the bottom of the stiff casing with an insert which includes a micro-opening, it is possible to adjust the time for pressure ~~equalisation~~ equalization between the gas space in the cartridge and the ambient atmosphere. For example with a volume of 3 millilitres of the gas space in the cartridge and a pressure difference of 20 hPa (20 mbar) between the ambient atmosphere around the cartridge and the gas space in the cartridge, in the case of a circular micro-opening of a length of 200  $\mu$ m and a diameter of between 80  $\mu$ m and 50  $\mu$ m, it is possible to achieve a half-value time for pressure ~~equalisation~~ equalization of between 2 hours and 13 hours.

In the case of a pressure ~~equalisation~~ equalization time which is adapted to the usual time interval between two operations of drawing off liquid from the cartridge, the diffusion of constituents of the liquid out of the collapsed bag is made more difficult.

The cartridge according to the invention can be for example 55 mm in length and 17 mm in diameter. The stopper can have an insertion connection portion whose inside diameter gives a firm press fit on a dispensing connection portion of an outside diameter of 2 mm.

The cartridge according to the invention can be used in an ~~atomiser~~ atomizer as is shown in Figures 6a and 6b in WO - 97/12687. The cartridge (1) of the present invention corresponds to the supply container (71) in Figures 6a and 6b, the spring portion of the locking clamping mechanism, in the form of connection portion (2), corresponds to the spring portion (56), and the lower portion (3) of the device corresponds to the lower housing portion (70).

The cartridge may contain an aqueous or alcoholic liquid.

When an aqueous liquid is involved, the container which is stable ~~in~~ with respect ~~of~~ to shape and the stopper can comprise polypropylene. The collapsible bag can comprise polyethylene. The stiff casing can comprise plastic material, preferably polypropylene. The opening in the bottom of the stiff casing can be a bore. The stopper for the container which is stable ~~in~~ with respect ~~of~~ to shape can be provided with an insertion connection portion which, at its end towards the internal space, can be closed with a diaphragm which is inclined relative to the axis of the insertion connection portion. The insertion connection portion can involve a press fit for the dispensing connection portion. The stopper can be connected to the container which is stable ~~in~~ with respect ~~of~~ to shape by a snap connection. The releasable plug-in connection between the cartridge and the connection portion of the dispensing device can be a

snap connection in which the snap hooks in the connection portion of the dispensing device engage into the peripherally extending groove in the upper region of the cartridge. the inside of the bottom of the lower portion of the device which is fitted on the upper portion can be provided with a resilient piercing device for the sealing foil on the underside of the bottom of the casing.

In the case of an alcoholic liquid the container which is stable ~~in~~ with respect ~~of~~ to shape and the stopper can comprise polypropylene. The collapsible bag can comprise polyethylene. The stiff casing can comprise metal, preferably ~~aluminium~~ aluminum. The recess in the bottom of the stiff casing may receive an insert with a micro-opening which communicates with the bore in the bottom of the casing. The stopper provided with an insertion connection portion, for the container which is stable ~~in~~ with respect ~~of~~ to shape, can be closed at its end towards the internal space by a diaphragm which is inclined with respect to the axis of the insertion connection portion. The insertion connection portion can be provided with a sealing closing ~~centred~~ centered guide means for the dispensing connection portion, the guide means being in the form of a press fit. The stopper can be non-releasably connected to the container which is stable ~~in~~ with respect ~~of~~ to shape, by means of the stiff casing. The releasable plug connection between the cartridge and the connection portion of the dispensing device can be a snap connection in which the snap hooks in the connection portion of the dispensing device engage into the peripherally extending groove in the upper region of the cartridge. The inside of the bottom of the fitted-on lower portion of the device can be provided with a resilient piercing device for the sealing foil on the underside of the bottom of the casing.

The cartridge according to the invention can be filled with a medical liquid which for example contains a pharmacologically active substance and for example water, ethanol or mixtures thereof.

WO - 98/27959 describes ~~stabilised~~ stabilized aqueous medicament preparations for producing propellant gas-free aerosols for inhalation. Attention is directed to the formulations which are claimed therein and set forth in the Examples.

Suitable medicament preparations in an ethanol solution are set forth for example in WO -97/01329, and in particular attention is directed to the active substances referred to therein (see therein pages 2 and 3) and the ~~stabilised~~ stabilized formulations claimed therein.

As medical active substances it is possible to use Berotec (Fenoterol hydrobromide); 1-(3,5-dihydroxy-phenyl)-2-[[1-(4-hydroxy-benzyl)ethyl]-amino]-ethanol hydrobromide), Atrovent (Ipratropium bromide), Berodual (combination of Fenoterol hydrobromide and

Ipratropium bromide), Salbutamol, Salbutamol sulphate, Combivent, Oxivent (Oxitropium bromide), Ba 679 (Tiotropium bromide), BEA 2108 (di-(2thienyl)-glycolic acid tropenol ester), Flunisolid, Budesonid, Beclomethasone and others.

The cartridge according to the invention enjoys the following advantages:

- The concentration of the medical liquid contained in the sealed cartridge varies only to a tolerable extent even over a storage time of several years and at elevated storage temperature.
- The content of the cartridge is highly effectively protected from contamination.
- The cartridge when fitted into the dispensing device can be used over several months.
- The half-value time for pressure ~~equalisation~~ equalization can be adjusted by the shape of the micro-opening.
- The cartridge can be produced in medically acceptable form.
- The unmodified original condition of the cartridge and the content thereof can be readily perceived within the specified period of usability by virtue of the intact sealing foils.
- The cartridge has a high degree of functional reliability; mishandling is avoided.
- The cartridge is securely held in the dispensing device.
- The fixedly closed cartridge is child-proof and makes it more difficult to manipulate the content thereof.
- The empty cartridge can be easily pulled out of the dispensing device because of the ridge at the bottom of the stiff casing;

The cartridge according to the invention which contains a medical liquid can be used to produce an inhalable aerosol by means of an ~~atomiser~~ atomizer. The aerosol can serve for treating illnesses.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view of a cartridge of the present invention and a connection portion and lower portion of a draw-off of dispensing device connected to the cartridge.

FIG. 2 is a cross-sectional view as in FIG. 1, with the cartridge completely pushed into the connection portion and lower portion of the dispensing device.

FIG. 3a is an enlarged cross-sectional view of the lower portion of the dispensing device and the lower end of the cartridge.

FIG. 3b is an enlarged cross-section view as in FIG. 3a with the piercing device having pierced the sealing foil.

FIG. 4a is a cross-section through a withdrawal aid fitted on the cartridge of the invention.

FIG. 4b is a plan view of the withdrawal aid fitted onto the cartridge with the stiff over casing in cross-section.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The cartridge according to the invention is described in greater detail by means of the drawings.

Figure 1 shows the cartridge 1, the connection portion 2 of the draw-off or dispensing device and the lower portion 3 of the device which is pushed over the connected cartridge. The stiff casing 4 contains the container 5 which is stable ~~in~~ with respect ~~of~~ to shape, with the collapsible bag 6. The container ~~which is stable in respect of shape~~ 5 is closed by the stopper 7 and the snap connection 8. Disposed between the upper edge of the container ~~which is stable in respect of shape~~ 5 and the underside of the stopper 7 is the sealing disc 9 into which the sealing lip 10 is pressed. The stiff casing 4 includes the peripherally extending groove 11 against which the lower edge of the stopper 7 bears. The peripherally extending crease 12 in the stiff casing 4 is pressed into the stopper 7. The stopper 7 is held at its top side by the flanged-over portion 13 of the upper end of the stiff casing 4. The opening 14 is provided in the container 5 ~~which is stable in respect of shape~~.

The connection portion 2 of the dispensing device includes the dispensing or draw-off connection portion 15 which has already pierced the sealing foil 16 on the top side of the stopper 7 and which has penetrated into the insertion connection portion 17. When the cartridge 1 is further pushed onto the dispensing connection portion 15 it penetrates the region 17a of the press fit and pierces the inclined diaphragm 18 at the end of the insertion connection portion 17. The snap hooks 19 on the connection portion 2 of the dispensing device engage from the outside into the peripherally extending groove 11 in the stiff casing 4.



The stiff casing 4 is provided in its central region with projections 4a which are disposed in a plane which is perpendicular to the axis of the casing. Those projections support the container ~~which is stable in respect of shape~~ 5.

The stiff casing 4 is provided at its bottom edge with the projecting ridge or bead 20. Disposed in the ~~centre~~ center of the recess in the form of the inwardly inverted region 21 is the opening 22 in the stiff casing 4. The bottom of the stiff casing 4 is covered by the sealing foil 23. The free space 24 is to be found between the sealing foil 23 and the inwardly curved region. The resilient piercing device 25 is disposed on the inside of the lower portion 3 of the dispensing device.

Figure 2 shows the cartridge 1 when it has been completely pushed onto the dispensing connection portion 15 and connected to the connection portion 2. The inclined diaphragm 18 at the end of the insertion connection portion 17 is pierced and the snap hooks 19 engage into the peripherally extending groove 11 at the upper end of the stiff casing. The stopper 7 is provided with guide ribs 7a. The region 17a involves a press fit between the dispensing connection portion 15 and the stopper 7. The insert 26 is disposed in the recess in the form of the inwardly inverted region 21 of the bottom of the stiff casing 4.

Figure 3a shows the end of the stiff casing 4, the end of the lower portion 3 of the dispensing device and the insert 26 on an enlarged scale. The insert 26 includes the micro-opening 27 which communicates with the opening 28 in the bottom of the stiff casing 4. Disposed in front of the micro-opening is the filter 29. The bottom of the stiff casing is covered by the sealing foil 23.

Figure 3b shows the condition in which the piercing device 25 has pierced the sealing foil 23.

Figure 4a shows a cross-section through the withdrawal aid 30 which is fitted onto the cartridge 1 and which has pressed the stiff casing 4 in, behind the ridge or bead 20. The cartridge 1 is clamped in position in the withdrawal aid 30 and can be turned about the axis of the cartridge and pulled out of the dispensing device by means of the withdrawal aid 30.

Figure 4b shows a view from above of the withdrawal aid 30 in the condition of being fitted on the cartridge and the stiff casing 4 in cross-section. The withdrawal aid 30 includes an opening with a centrally arranged region whose diameter is substantially the same as the outside diameter of the stiff casing 4 and which is smaller than the diameter of the bead or ridge 20. The central region of the opening goes into an enlarged opening 31 so that the withdrawal

aid 30 can be easily fitted onto the end of the cartridge. The diameter of the central region of the opening is reduced at two mutually ~~diametrically~~ diametrically oppositely disposed locations 32 and 33 and the circular arc of the opening is flattened. At those locations, the stiff casing of the cartridge is compressed when the withdrawal aid 30 is pushed on, whereby a tight connection is made between the withdrawal aid and the cartridge 1.

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